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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/428,082	10/22/99	FEIGE	U A-527

EXAMINER

HUFF, S

ART UNIT	PAPER NUMBER
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021069
AMGEN INCORPORATED
MAIL STOP 27-4-A
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

1- File Copy

Office Action Summary	Application No. 09/428,082	Applicant(s) FEIGE ET AL.	
	Examiner Sheela J Huff	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11,22-25 and 52* is/are pending in the application.

4a) Of the above claim(s) *7,9,11 and 22-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 February 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *03 February 2001* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-21 and the election of SEQ ID No. 213 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the examiner in the PCT application determined that there were three groups and that the examiner in the instant application should abide by this. This is not found persuasive because the instant case is a US case and as such all of the sequences would need to be searched and to search the multitude of peptides in the present case is clearly a burden.

The requirement is still deemed proper and is therefore made FINAL.

Claims 8, 12-21 and 26-51 have been cancelled.

Claims 7 ,9, 11 and 22-25 are directed to a non-elected invention.

Claims 1-6 and 10 and 52 (as they read on SEQ ID No. 213) are currently under consideration.

Information Disclosure Statement

Copies of the initialed PTO-1449 filed 1/17/01 and 10/22/99 are enclosed.

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on 2/3/01 have been approved.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 4 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bendele et al, WO 98/24477 or Collins et al WO 97/28828 alone ~~or in view of Kohler WO 99/14244~~ (3/25/99).

Bendele et al and Collins et al both disclose a carboxy-terminus modified chimeric protein which is a fusion of IL-1ra and "all or part of the constant domain of the heavy or light chain of human immunoglobulin" and the immunoglobulin can be IgG1

(see paragraph bridging pages 11-12 of Bendele et al and pages 12-13 of Collins et al). The chimeric protein can be used in the treatment of inflammatory disorders. This reads on applicant's invention when c=0.

They only difference between the claimed invention and the references is that the references do not specifically make the suggested chimeric protein and that the claims encompasses the use of a linker (ie c=1).

However, in view of the clear suggestion in the references to make such polypeptides it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to make the chimeric proteins and to use the chimeric proteins to treat inflammatory disorders. The use of linkers to produce chimeric proteins is very well known in the art (see Kohler) and therefore the use of a linker is within the purview of one skilled in the art.

1-3,5-6, 10, 52

Claims 1-6 and 10 and 52 (as they read on SEQ ID No. 213) are rejected under 35 U.S.C. 103(a) as being unpatentable over Bendele et al, WO 98/24477 or Collins et al WO 97/28828 in view of ~~Kohler WO 99/14244~~, Yanofsky et al US 5608035 and Brems et al WO 98/46257.

Bendele et al, Collins et al and Kohler have been discussed above.

The only difference between the instant invention and the reference is that the claims require SEQ ID No. 213.

Seq ID No. 11 and 256 (which are Il-1 antagonists) in Yanofsky et al read on SEQ Id No. 213 of the instant invention.

Brems et al discloses that it is well known in the to increase the half-life or to incorporate functions as such as Fc receptor binding into therapeutic proteins (page 3, lines 12-15).

Therefore, in view of Yanofsky et al and Brems et al, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to replace the Il-1ra portion of the chimeric peptide in Collins et al or Bendele et al with SEQ ID No 11 or 256, to increase the half-life of the peptide or to incorporate functions as such as Fc receptor binding into the peptide. The use of linkers to produce chimeric proteins is very well known in the art ~~(see Kohler) a~~nd therefore the use of a linker is within the purview of one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on M,Th 5:30 am-2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sheela J Huff
Primary Examiner
Art Unit 1642

sjh
August 27, 2001